

§§ 900.8–900.9 [Reserved]

**Subpart B—Quality Standards and Certification****§ 900.10 Applicability.**

The provisions of subpart B are applicable to all facilities under the regulatory jurisdiction of the United States that provide mammography services, with the exception of the Department of Veterans Affairs.

**§ 900.11 Requirements for certification.**

(a) *General.* After October 1, 1994, a certificate issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart. To obtain a certificate from FDA, facilities are required to meet the quality standards in § 900.12 and to be accredited by an approved accreditation body or other entity as designated by FDA.

(b) *Application*—(1) *Certificates.* (i) In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity designated by FDA. The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).

(ii) Following the agency's receipt of the accreditation body's decision to accredit a facility, or an equivalent decision by another entity designated by FDA, the agency may issue a certificate to the facility, or renew an existing certificate, if the agency determines that the facility has satisfied the requirements for certification or recertification.

(2) *Provisional certificates.* (i) A new facility beginning operation after October 1, 1994, is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional certificate, a facility must meet the requirements of 42 U.S.C. 263b(c)(2) and submit the necessary information to an approved accreditation body or other entity designated by FDA.

(ii) Following the agency's receipt of the accreditation body's decision that

a facility has submitted the required information, FDA may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements of § 900.11(b)(2)(i). A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90-day extension of the provisional certificate.

(3) *Extension of provisional certificate.*

(i) To apply for a 90-day extension to a provisional certificate, a facility shall submit to its accreditation body, or other entity designated by FDA, a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

(ii) The accreditation body shall forward the request, with its recommendation, to FDA within 2 business days after receipt.

(iii) FDA may issue a 90-day extension for a provisional certificate upon determination that the extension meets the criteria set forth in 42 U.S.C. 263b(c)(2).

(iv) There can be no renewal of a provisional certificate beyond the 90-day extension.

(c) *Reinstatement policy.* A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may be considered to be a new facility and thereby be eligible for a provisional certificate.

(1) Unless prohibited from reinstatement under § 900.11(c)(4), a facility applying for reinstatement shall:

(i) Contact an FDA-approved accreditation body or other entity designated by FDA to determine the requirements for reapplication for accreditation;

(ii) Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

(A) Name and address of the facility under which it was previously provisionally certified or certified;